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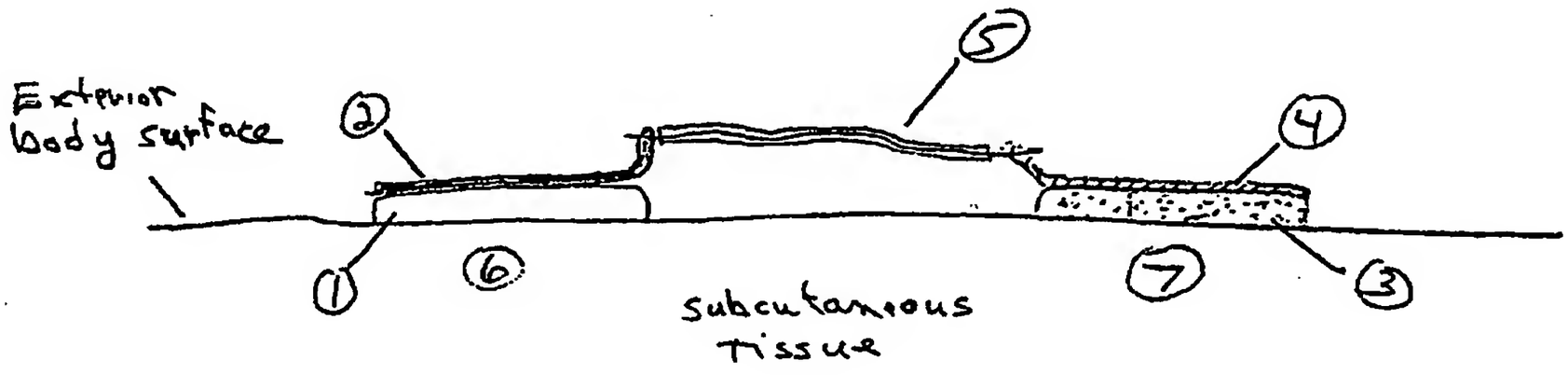
(54) Title: DEVICES AND METHODS FOR THE GENERATION OF VOLTAGE POTENTIAL



(57) Abstract: Device for generating a voltage potential on a body and causing a direct current to flow in the body, comprising a first electrode/electrolyte pair and a second electrode/electrolyte pair of different electrode potentials, the electrolyte of the first electrode/electrolyte pair in ionic contact with a first region of the body, the electrolyte of the second electrode/electrolyte pair in ionic contact with a second region of the body, and an conductor establishing an electrical connection only between the electrodes of the first and the second electrode/electrolyte pairs.

DESCRIPTION

DEVICES AND METHODS FOR THE GENERATION OF VOLTAGE POTENTIAL

FIELD OF THE INVENTION

This invention relates to devices and methods to generate voltage potentials which results in the flow of electrical currents in the body.

BACKGROUND OF THE INVENTION

The following is a discussion of the relevant art, none of which is admitted to be prior art to the inventive subject matter herein disclosed.

Accelerated wound healing has been found with the application of electric current to the wound site (Wolcott et al., Southern Medical Journal, 62:797, 1969; Rowley et al., Annals New York Academy of Sciences, p. 543, 1974; Rowley et al., ISA BM, 74322:111, 1974). Low intensity electric currents have been used to treat chronic or slow healing wounds and to treat pain (Carley et al., Arch. Phys. Med. Rehabil., 66:443, 1985). Typically, treatment involves the use of electrical devices external to the body which provide electrical current to the body through attached electrode. An electrostatic field has been applied to an injury site using an electret device (U.S. Patent No. 4,142,521). Charged gold leaf has been used to prevent scarring in small pox. It has been suggested that the mechanism of action involved an electrochemical influence of gold.

The phenomena of enhanced wound healing with the use of electricity has been explained in various ways. The presence of biological currents which occur after injury, called currents of injury (COI), were first described by Galvani and have been demonstrated in many studies (Becker et al., Nature, 156:675, 1962; Becker, Medical Times, 75:657, 1967). Injury currents are weak electrical currents which can be measured in newly injured skin and subcutaneous tissues. These weak electrical currents are not observed in chronic or non healing wounds. It is

hypothesized that reestablishing the injury current allows the wound healing process to resume.

Electrochemical cells (batteries) utilize oxidation and reduction (redox) reactions which involve the transfer of electrons from one chemical substance to another. Oxidation occurs when a chemical substance loses electrons and reduction occurs when a chemical substance gains electrons. Chemical substances undergoing redox reactions are referred to as oxidants when accepting electrons and reductants when donating electrons. An example of a redox reaction would be zinc (solid) oxidized by copper ion (in aqueous solution).

$$Zn_{(solid)} + Cu^{++}_{(aqueous)} \longrightarrow Zn^{++}_{(aqueous)} + Cu_{(solid)}$$

The solid metal zinc (Zn) electrode is ionized (and dissolved into solution) and donates two electrons to the copper ion (Cu^{++}) in solution which is then deposited as a solid layer on the zinc electrode. In this reaction the zinc electrode is oxidized by the copper ion, and the copper ion is reduced by the zinc. A redox reaction may be described by two half reactions, with one species being oxidized and another being reduced.

$$Zn_{(solid)} \longrightarrow Zn^{++}_{(aqueous)} + 2e^{-} \qquad \underline{\text{Oxidation Half Reaction}}$$

$$Cu^{++}_{(aqueous)} + 2e^{-} \longrightarrow Cu_{(solid)} \qquad \underline{\text{Reduction Half Reaction}}$$

A property of redox reactions is such that each half reaction may proceed without the two components, i.e., the oxidation half reaction and the reduction half reaction, being in direct physical contact. The physically separate half reactions (comprised of an electrode/electrolyte pair) may proceed when the electrodes of each half reaction are connected directly to one another by a conductor and when the electrolytic solutions of each half reaction are connected by a salt bridge. Using the above example of zinc and copper, an electrochemical cell or battery can be

created by immersing a solid zinc electrode in an electrolytic solution and by immersing a solid copper electrode in a separate copper ion solution. Connecting the two solutions with a salt bridge creates a measurable voltage potential between the two half reaction cells. If the two electrodes are then connected via a conductor, e.g., a wire, electrons would flow through the conductor in one direction and ions would flow between the two solutions thorough the salt bridge. A current of electricity is thus established through the conductor.

This is the basis for chemical cells or batteries that produce a voltage potential and current. The electrode voltage potential of a chemical cell will be determined by the difference of the individual half cell electrode voltage potentials. Designation as an oxidant or reductant is determined by the relative reduction potential of each half reaction. Thus a species whose half reaction reduction potential is higher than that of a second species reduces the latter and is deemed to be the stronger reductant. Similarly, a species whose half reaction reduction potential is lower than that of a second species oxidizes the latter and is deemed to be the stronger oxidant.

The standard half reaction electrode voltage potential of various chemicals undergoing oxidation or reduction in standard solutions have been measured against a standard hydrogen electrode and tabulated in charts. The half reaction electrode voltage potential of non-standard solutions can be calculated using the Nernst Equation and may be directly measured. Electrochemical cells with significant voltage potential may also be created from electrolytic solutions of a single species using different concentrations (concentration cell).

SUMMARY OF THE INVENTION

The present invention produces direct current to flow in the body by using two electrode/electrolyte pairs of different half cell potentials positioned separately on the body. The electrode/electrolyte pairs are comprised of a solid electrode in physical contact with an electrolyte solution, which may be in the form of a gel. The present invention is in distinction to existing devices, as there is no external power source, such as a battery, used to deliver current to the body.

Thus, in a first aspect, the present invention features a device for generating a voltage potential on a body and causing an electrical current to flow in the body, comprising: (a) a first electrode, (b) a second electrode, (c) a first electrolyte, and (d) a second electrolyte, where (i) the first electrode and the first electrolyte form a first electrode/electrolyte pair, (ii) the second electrode and the second electrolyte form a second electrode/electrolyte pair, (iii) the first electrode/electrolyte pair has a different electrode voltage potential than the second electrode/electrolyte pair, (iv) the electrolyte of the first electrode/electrolyte pair is in ionic contact with a first region of the body, (v) the electrolyte of the second electrode/electrolyte pair is in ionic contact with a second region of the body, and (vi) the first electrode is in contact with the second electrode, where the contact establishes an electrical connection only between the electrodes of the first and the second electrode/electrolyte pairs; or provided that there is no external power source.

"Generating" in the context of the present invention means to cause or produce a voltage potential. By "voltage potential" it is meant the driving force on the electrons in a galvanic cell or a battery, or an electric circuit in general, which causes the electrons to move from one location to another within the circuit. The circuit may be composed of two half reaction cells in a galvanic cell, in addition to a salt bridge and a wire connecting the two electrodes. The voltage potential of a cell is also call the "cell potential" or the "electromotive force" of the cell. Voltage potentials are usually measured in units of volts.

In a galvanic cell, which comprises two half reaction cells, each half reaction cell, also known as half cell, has an electrode voltage potential, which is measured in comparison to the standard hydrogen electrode. The voltage potential for a galvanic cell is the sum of the two half cell electrode voltage potentials.

"Body" means the body of an animal being treated by the device and the methods of the present invention. The animal may be a fish, reptile, amphibian, bird, or mammal. Mammals comprise a large group of animals. Some preferred mammals that may be treated by the device and the methods of the present invention include, but are not limited to, mice, rats, rabbits,

guinea pigs, sheep, goats, pigs, horses, mules, cows, and more preferably cats, dogs, monkeys, apes, and most preferably humans.

An "electrical current" in the context of the present invention may include the flow of electrons in a conducting materials and the flow of ions through a medium, such as a solution, gel, or oil. Thus, the movement of ions in an aqueous solution in the presence of an electrical field, the movement of charged molecules through agar gel, and the movement of electrons in a wire represent examples without limitation of electrical current.

An "electrode" is a substance in its elemental form which in combination with an electrolyte in a galvanic cell can either be oxidized and be depleted, oxidize another material, or reduce another material, which may or may not plate over the electrode. An electrode conducts electrons to or from its surface during oxidation or reduction reactions and may undergo degradation or reconstitution by participating in oxidation or reduction reactions. The electrode may be a metal, such as copper, zinc, platinum, aluminum, etc., or a non-metal, such as carbon. The electrode at which oxidation occurs is called the anode and the electrode at which reduction takes place is called the cathode. Thus, the anode is negatively charged whereas the cathode is positively charged.

"Electrolytes" are solutions, usually aqueous solutions, i.e., those which are made of water, which contain dissolved charged particles, or ions. Electrolytes may also be composed of gels, pastes, oils, oil emulsions, or other viscous material in which charged particles can be dissolved. An example of an electrolyte solution is an aqueous solution of zinc chloride, where the salt, i.e., zinc chloride, dissociates into zinc cations and chloride anions. Electrolytes conduct electricity since the dissolved charged particles can move within the solution when an a voltage potential is applied; cations move towards the cathode and anions move towards the anode.

In the present invention electrolyte solutions are preferably contained in a matrix such as cotton wadding, gauze, open cell foam, or in a gel suspension or polymer or thickening agent to improve ease of handling and when desirable to provide adhesion between the electrolytic solution and the electrode and between the electrolytic solution and the body, e.g., skin or

wound.

When an electrode is in contact with an electrolyte, one obtains an "electrode/electrolyte pair." In an electrode/electrolyte pair an electrode is in contact with an electrolyte solution so that the donation or acceptance of electrons by the electrode will cause one half of a redox reaction to occur at the electrode surface. The voltage potential (the propensity for donating or accepting electrons) of an electrode/electrolyte pair may be measured relative to a second electrode/electrolyte pair when the electrolytes of two electrode/electrolyte pairs are connected by an ionic (salt) bridge. Examples of electrode/electrolyte pairs include, but are certainly not limited to, a zinc strip in an aqueous solution of zinc chloride, a copper wire in an aqueous solution of copper chloride, or a piece of graphite in an acidic solution.

By "first electrode/electrolyte pair" is meant an electrode/electrolyte pair that has an electrode voltage potential that is either higher or lower than a second electrode/electrolyte pair, such that when the electrolytes of the first and the second electrode/electrolyte pairs are connected by a salt bridge a differential electrical potential (voltage) is established causing a flow of electrons between the two electrodes. An electrode/electrolyte pair with a higher (more positive) electrode voltage potential will accept electrons from an electrode/electrolyte pair with a lower (less positive) electrode voltage potential. By convention electric current is a positive flow which is in the opposite direction from electron flow. Thus electric current will flow from a more positive electrode to a less positive (more negative) electrode.

The "second electrode/electrolyte pair" is an electrode and electrolyte solution that is different from the first electrode/electrolyte pair, either in its chemical composition or in the concentration of its substituents, and thus will have an electrode voltage potential that is either higher or lower than the first electrode/electrolyte pair.

By "different electrode voltage potential" is meant that one of the two electrode/electrolyte pairs has a higher or lower electrode voltage potential than the other such that when the two electrodes are electrically connected there will be an electric current generated.

By "contact" in the context of the present invention it is meant the attachment of two

electrodes or electrolytes such that electrons can move between them. If two electrodes are attached via a wire, then they are in contact with each other. Similarly if the two electrodes are directly touching each other, then they are in "direct contact" with each other. A single electrode can act as two electrodes which are in contact with each other if two different parts of the same piece of electrode material touch two different electrolytes, which in turn are not in contact with each other, except for the electrode material and a salt bridge.

If two electrodes or electrolytes are in contact with each other such that, instead of electrons flowing between them, ions flow between them, then the two electrodes or electrolytes are in "ionic contact" with each other. While in ionic contact, the electrolytic solution of the electrode/electrolyte pair is physically touching the body (e.g., skin or wound) so that ions can pass from the body into the electrolyte solution or from the electrolyte solution into the body. Ionic contact may be made directly with the body or established indirectly by having the electrolyte solution in direct contact with a second electrolyte material acting as an ionic transfer material, such as an ionic gel, that is in direct contact with the skin or wound.

A "salt bridge" is device which connects two electrolytes with each other and allows for ions to move from one electrolyte to another. A salt bridge may be a U-shaped tube filled with an electrolyte, or a porous membrane which separates the two electrolytes, or a mammalian tissue which contains salts. The tissue may contain blood, plasma, cytoplasmic fluids, etc., which allow for ions to move within the tissue when a voltage potential is applied. It is understood that all bodily fluids and tissues are electrolytic in nature and can act as a salt bridge for the purposes of this invention.

By "first region" and "second region" is meant that the electrolytic portion of the electrode/electrolyte pairs are physically separate from each other and not in contact with one another on the body so that ions cannot move directly from one electrolyte solution to the other without moving through the body. A region of a body is any exterior surface of the body on which the electrode/electrolyte pairs rest. For example, the epidermis or a cavity in the epidermis such as a wound bed, or a region that is a source of localized pain, or a region removed

from the wound bed or source of pain.

"Exterior surface of the body" is an area on the surface of the epidermis or skin or a wound site or any region of the body that can be contacted without the use of invasive procedures which compromises the integrity of the skin or deeper tissues.

"Wound bed" includes, but is not limited to, openings or lesions in cutaneous or subcutaneous tissues including bed sores, diabetic sores, vascular insufficiency lesions, surgical incisions, abrasions, cuts, punctures, blemishes, tears, sores, blisters, burns, contusions, tissue ruptures, and the like.

"Ionic gel" is a gel or other aqueous substance that can serve as a conductor of ions and/or as a barrier between the electrolyte and the body, if the electrolyte is not completely biocompatible. An ionic gel can itself be an electrolyte. An ionic gel in the context of the present invention is not oxidized or reduced, but contains ions. An ionic gel can also serve to establish an ionic connection between the electrolyte and the body. Examples of ionic gels include various dissolved salts in aqueous suspensions and mixtures including but not limited to colloids, alginic acid, aqueous polymers, and carbohydrates, such as pectin, agar, carboxymethylcellulose, gelatin, or other carbohydrate based mixtures.

In preferred embodiments, the contact between the first electrode and the second electrode is made by a conductor establishing an electrical connection only between the electrodes of the first and the second electrode/electrolyte pairs. The "conductor" is any material that can conduct electricity. Depending on the particular use, those skilled in the art know which material to use that would have the best resistance to electricity and also have other suitable qualities, such as malleability, ease of use, and cost. Some examples of suitable conductors include, but are not limited to, metallic wires, mesh, strips of metal, and the like. Preferably, the conductor is insulated by being encapsulated by a non conducting material (such as plastic, rubber, or nonionic gels). The conductor is thus prevented from making electrical or ionic contact with the body. The conductor may also be physically kept from making contact with the body, such as by being contained in a bandage that has portions which are not in contact with the

body surface.

In other preferred embodiments, the contact between the first electrode and the second electrode is made by a direct physical contact between the first and second electrodes. Another conductor is not required to connect the two electrodes. Such a direct contact establishes an electrical connection that allows a flow of electrons from one electrode to a second electrode. In a further preferred embodiment, there is an insulator positioned between the contact region of the electrodes of the first and second electrode/electrolyte pairs and the body.

Some preferred embodiments of the present invention provide that the first electrode/electrolyte pair has a higher electrode potential than the second electrode/electrolyte pair and is positioned on an exterior surface of the body in a wound bed or a region which is a source of pain. The second electrode/electrolyte pair is positioned on the exterior surface of the body on tissue surrounding the first region. In other preferred embodiments the first electrode/electrolyte pair has a lower electrode potential than the second electrode/electrolyte pair and is positioned on an exterior surface of the body in a wound bed or a region which is a source of pain and the second electrode/electrolyte pair is positioned on the exterior surface of the body on tissue surrounding the first region.

Furthermore, preferably the first electrolyte and the second electrolyte are of different chemical composition, such that the first electrolyte solution is in ionic contact with a first region of the body, and the second electrolyte is in ionic contact with a second region of the body, and the contact between the first electrode and the second electrode is made by having the first and second electrodes be one and the same, where a first position on the electrode is in ionic contact with the first electrolyte and a second position on the electrode is in ionic contact with the second electrolyte, the electrode not in ionic contact with the body.

By "different chemical composition" is meant that a first electrolyte will have a different oxidation or reduction potential when in contact with an electrode than a second electrolyte when in contact with the same electrode. The phrase "different chemical composition" encompasses two electrolytes that have the same chemical constituents, i.e., the same salt being dissolved in

water, but have a different concentration or pH. For example, two hydrogen peroxide containing solutions having different pH are deemed to be electrolytes of different chemical composition.

By "electrode not in ionic contact with the body" is meant that the electrode does not directly come in contact with the body or ionic gel, other than indirectly through the electrolytes.

As mentioned above, the first and second electrodes may be one and the same. In this case, the electrode comprises a strip of conducting material, one point of which is in contact with one electrolyte and another point of which is contact with another electrolyte. Preferably, there exists an insulating material, as described herein, between the two points of contact and the two electrolytes.

The device of the invention may preferably be a bandage which further comprises an inner surface and an outer surface.

A "bandage" is a material which can be affixed to the surface of the body so that the electrolytes of the first and the second electrode/electrolyte pairs make ionic contact with regions of the body. Bandages can be composed of sterile, adherent, and sometimes absorptive materials that attach to and cover an area of the body so as to prevent entry of foreign or infectious materials onto a wound or other area of the body and to prevent leakage of electrolytes or infectious fluids into a wound or other area of the body.

The "inner surface" of the bandage is that surface which contacts the body, while the "outer surface" faces away from the body. It follows, then, that a bandage has and area between the inner and outer surfaces which does not contact the body surface and lies below the outer surface.

In another aspect, the invention features a method for generating a voltage potential on a body and causing an electrical current to flow in the body, comprising (a) providing a first electrode; (b) providing a second electrode; (c) providing a first electrolyte; and (d) providing a second electrolyte; where (i) the first electrode and the first electrolyte form a first electrode/electrolyte pair; (ii) the second electrode and the second electrolyte form a second electrode/electrolyte pair; (iii) the first electrode/electrolyte pair has a different electrode voltage

potential than the second electrode/electrolyte pair; (iv) the electrolyte of the first electrode/electrolyte pair is in ionic contact with a first region of said body; (v) the electrolyte of the second electrode/electrolyte pair is in ionic contact with a second region of said body; and (vi) the first electrode is in contact with the second electrode. It is always the case that the contact between the first electrode and the second electrode establishes an electrical connection only between the electrodes of the first and the second electrode/electrolyte pairs, or that there is no external power source used in conjunction with the device of the present invention.

In a preferred embodiment, the contact between the first electrode and the second electrode is made by a conductor. The contact between the first electrode and the second electrode may also preferably be made by a direct physical contact between the first and second electrodes.

In other preferred embodiments, the above method is practiced such that (a) the first electrolyte and the second electrolyte are of different chemical composition, where (i) the first electrolyte solution is in ionic contact with a first region of the body, and (ii) the second electrolyte is in ionic contact with a second region of the body. Additionally, (b) the contact between the first electrode and the second electrode is made by having the first and second electrodes be one and the same, where a first position on the electrode is in ionic contact with the first electrolyte and a second position on the electrode is in ionic contact with the second electrolyte, the electrode not in ionic contact with the body.

In another aspect, the invention features a method for treating a patient with a condition amenable to treatment by the generation of a voltage potential and the flow of electrical current in the patient's body, or a method for promoting wound healing, or a method for promoting wound cleansing, all of which comprise the exercise of the method for generating a voltage potential on a body and causing an electrical current to flow in the body, as described herein.

A "condition amenable to treatment" is a condition which can be improved by the causing the flow of electrical current. Those of ordinary skill in the art are familiar with such conditions which include, but are not limited to, wound healing, wound cleansing, pain management, edema

reduction, and control of inflammation.

To treat the patient, a health-care professional or a patient may administer the methods and device of the invention such that a current suitable for therapy is applied to the patient. That level is a level of current which will result in an improvement in the condition. Those of ordinary skill in the art are familiar with such conditions and the level of current required for their treatment.

A "wound" is a disruption of the epidermis, dermis, or subcutaneous tissues causing exposure of tissues normally covered by skin such that the exposed tissues leak body fluids and become a source of bacterial colonization and infection. "Wound healing" comprises the process of closure of a wound including but not limited to the infiltration of white blood cells and fibrocytes, the growth of granulation tissue and epithelial tissues, wound retraction and the progressive reduction of exposed tissues. The reduction in wound exudate and reduction in wound bacterial counts is called "wound cleansing." "Exudate" is a body fluid highly suitable for bacterial growth which is released into wounds due to the exposure of tissues normally covered by skin.

Another aspect of the invention provides for a kit for generating a voltage potential on a body and causing an electrical current to flow in said body, comprising (a) a biocompatible first electrolyte; (b) a biocompatible second electrolyte, and (c) a biocompatible first electrode. The kit may preferably further comprise (d) a biocompatible second electrode; and (e) a conductor; where (i) the first electrode and the first electrolyte form a first electrode/electrolyte pair; (ii) the second electrode and the second electrolyte form a second electrode/electrolyte pair; and (iii) the first electrode/electrolyte pair has a different electrode voltage potential than the second electrode/electrolyte pair.

A "biocompatible" material is a material whose use in conjunction with biological materials, such as tissues, cells, organs, etc., does not adversely affect the constitution of the biological material. Furthermore, a biocompatible material does not typically trigger an immune response from the body of the animal to which the biocompatible material is administered.

Therefore, by way of example only, saline, aqueous sodium chloride solution, at certain concentrations is biocompatible since its introduction into the blood stream does not affect the constitution of the blood cells and other tissues. However, introduction of saline of low concentrations into the blood stream may cause red blood cells and other tissue cells to burst. Thus, low concentrations of saline are not biocompatible. The biocompatibility of certain salts or compounds and their aqueous concentrations are generally known to those of ordinary skill in the medical arts. It is also understood that the biocompatibility of certain materials is depended upon its application. Thus, for some applications a material may be biocompatible while for other applications the same material may not be biocompatible. For example, certain cremes or gels are biocompatible when administered topically but are not biocompatible when administered orally.

In some preferred embodiments, the kit further comprises a conductive ionic gel. The kit may also preferably comprise instructions for the placement of the first electrode and electrolyte, the second electrode and electrolyte, and the conductor on a body. The first electrode and the second electrode may preferably be metallic foils or carbon impregnated polymer or carbonized fabric. "Metallic foils" are thin sheet-like, malleable and conformable configurations of a metal, such as aluminum, nickel, tin, copper, gold, silver, iron or alloys of metals. The first and second electrolytes may preferably be contained in a matrix, where the matrix is preferably selected from the group consisting of an aqueous polymer or carbohydrate gel, a paste, saturated gauge, and open cell foam.

In more preferred embodiments, the first electrode is a metallic foil, where the metal is preferably selected from the group consisting of nickel, copper, tin, zinc, and aluminum. The first electrolyte is preferably selected from the group consisting of sodium chloride, magnesium hydroxide, sodium bicarbonate, and calcium carbonate, or other ionic and/or weakly basic solutions that are biocompatible and enhance the oxidation of a metallic electrode.

In other preferred embodiments, the second electrode is a carbon impregnated polymer, paired with a second electrolyte selected from a group of solutions comprised of sodium

chloride, hydrogen peroxide in a weakly acidic solution, iodine, acetic acid, ascorbic acid or other dilute or weakly acidic solutions that will undergo reduction at the carbon electrode. Alternatively, the second electrode/electrolyte pair may be comprised of a conductive polymer coated with silver, and the salt of silver chloride. When paired with an electrolyte solution the dissolved silver ion will redeposit on the silver electrode causing oxidation.

The summary of the invention described above is non-limiting and other features and advantages of the invention will be apparent from the following description of the preferred embodiments, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a diagrammatic representation of one configuration of the present invention in which the electrodes of the electrode/electrolyte pairs are connected by an insulated conductor.

FIG. 2 is a diagrammatic representation of one configuration of the present invention in which the electrodes of the electrode/electrolyte pairs are in direct contact.

FIG. 3 is a diagrammatic representation of one configuration of the present invention in which a single conductive material forms the electrode of both electrode/electrolyte pairs.

FIG. 4 is a diagrammatic representation of one configuration of the present invention in which one of the electrode/electrolyte pairs is positioned in a wound bed.

FIG. 5a and 5b are diagrammatic representations of a configuration of a bandage of the present invention. FIG. 5a is a side view of the bandage. FIG. 5b is a bottom view of the bandage.

FIG. 6 shows a concentric configuration of the device, both side view and bottom view.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

I. Devices and Methods of Use

The devices and methods of the present invention are based on the principle of two

electrode/electrolyte pairs undergoing half reactions. The electrode/electrolyte pairs are comprised of an electrode in direct contact with an electrolyte solution capable of undergoing an oxidation or reduction reaction. The electrolyte solutions are in ionic contact with the body directly or through some ionic medium. Preferably, the ionic medium is an ionic gel positioned between the electrolyte and the body. The ionic gel serves to improve the ionic contact between the body and the electrolyte and also prevents migration of reagents from the electrolyte into the body. The electrolyte solutions of each electrode/electrolyte pair are physically separate from one another on the body such that ions flow from one electrolyte to another must travel through the body, which is acting as a salt bridge. The electrodes of each electrode/electrolyte pair are electrically connected to each other directly or through a conductor, but are not in contact with the body except, indirectly through the electrolyte solutions.

For example, for current to flow in and around a wound site, one electrode/electrolyte pair is positioned in the wound bed or in ionic contact with the surface of the wound and the other electrode/electrolyte pair is placed on the body in ionic contact with the skin at a separate location from that of the first electrode/electrolyte pair. For a wound site, the salt bridge consists of the wound itself and the tissues between the wound and the second electrode/electrolyte pair. The electrolyte solutions of the two electrode/electrolyte pairs although physically separated are in continuous ionic connection through the body acting as a salt bridge.

The voltage produced by the claimed invention is determined by the difference in half cell electrode voltage potentials of the two electrode/electrolyte pairs. The electrode voltage potentials of each electrode/electrolyte pair is determined by the specific chemical constituents and their concentrations. The current produced by the claimed invention is determined by the difference in electrode voltage potentials, electrode surface areas, and resistance to ion migration caused by solutions, ionic contact medium, and body tissues.

The polarity of the device is a function of electrode potentials such that the electrode/electrolyte pair with the higher electrode potential has a positive polarity (anode) and the electrode/electrolyte pair with the lower electrode potential (cathode) has a negative polarity.

By convention, current in a conductor flows from higher to lower polarity.

The electrode can be provided as materials such as a metal foil, film, wire, mesh, or as waxes, pastes, or fabrics of various conductors, including carbon or other suitable substances. The electrolyte can be provided, for example, in an aqueous solution contained in a matrix such as cotton fiber, polymer foam, or as a gel formed from colloid suspension or aqueous carbohydrate polymers or other suitable delivery forms.

Many elements and compounds and their ions undergo redox reactions. Many of these substances are nontoxic and nonirritating and thus are biocompatible and suited for use as electrodes or electrolytes in the present invention. Biocompatible substances that may be used as electrodes in the current invention include, but are not limited to, aluminum, tin, copper, and silver, platinum, zinc, silver-silver chloride, carbon, carbon impregnated polymers and waxes, carbonized fabrics and carbon pastes. Biocompatible solutions that may be used as electrolytes in the current invention include, but are not limited to, aqueous solutions containing appropriate concentration of sodium chloride, magnesium hydroxide, sodium bicarbonate, aluminum acetate, carbamide peroxide, hydrogen peroxide, iodine, acetic acid, and ascorbic aid, or other salts, acids, or bases.

The selection of electrode materials and electrolyte solutions for electrode/electrolyte pairs which result in suitable potentials and currents and the appropriate positioning of electrode systems on the body as described in the present invention, allows for the generation of voltage potential and the flow of current in and around a wound bed or other body region (site of localized pain) which may derive therapeutic benefit from the flow of direct current.

One advantage of the present invention is that it can produce a direct current without the need for external apparatus such as conductive leads, electronic circuits, external batteries or other current producing and delivering devices. Wires can be a source of electrical failure and may result in skin irritation or breakdown due to pressure applied when the wires are sat upon or laid upon inadvertently. In addition, external batteries or other current generating devices represent an inconvenience and potential source of device failure or skin irritation for a patient.

Another advantage of the present invention involves the duration of use. Many conventional electrical therapeutic devices (such as those for use in wound healing) are typically only utilized for 15 to 30 minutes one or two times per day, because of need for set up and take down by a professional and inconvenience of having the equipment attached to the body for long periods of time. In certain circumstances longer term treatment would better facilitate wound healing and cleansing. The device of the claimed invention may be placed over a wound or in a wound bed and left in place for a long period of time, such as 12 or 24 hours, or until the next dressing change. Also, there is no need for determining a treatment time as is required in other electrical healing devices, as the treatment is self limited by the chemical makeup of the constituents. Once the chemicals are depleted, the generation of current, at the required level, no longer occurs. The disconnect step required in conventional electrical healing devices will also not be required. Also, chronic conditions such as diabetic foot ulcers, chronic decubitus ulcers, and localized pain syndromes require one or more treatments per day over many months. The device of the present invention simplifies the presentation of long term treatment.

A further advantage offered by the present invention is the ability of the constituent parts to conform to various anatomical shapes depending on the location of the body requiring treatment. Thus, the present invention may result in a more intimate fit with the body resulting in a greater degree of comfort for the patient. The present invention also allows for placement of the electrode/electrolyte pairs in a configuration that more specifically and accurately causes current to flow in a region of the body which may derive benefit from such current flow.

Also, compared to conventional wound dressings, a dressing that includes the present invention should require less frequent bandage changes. The frequency of bandage changes in chronic wound treatment is dictated in part by the presence of wound exudate which soaks and soils the bandages. The presence of wound exudate is due to bacterial colonization and chronic inflammation. Electrical stimulation of wounds results in virtual sterilization of surface wounds and contributes to reduced inflammation.

Other advantages of the present invention, is that the material useful for the construction

of the devices are readily available and inexpensive. Also, that the set up and configuration of the devices is very easy.

Thus, compared with standard electrical medical devices, there is a significant improvement in ease of use, lower cost and improved efficacy. One use of the claimed devices and methods is in the healing of chronic wounds. However, other common maladies which respond to electrical stimulation include, but are not limited to: osteoarthritis, lower back pain, other chronic pain syndromes, edema due to inflammatory conditions, and rheumatoid arthritis which commonly affect selected joints, bursitis, tendonitis and headaches are suitable for treatment using the claimed invention.

II. Matrices

In preferred embodiments, the first and second electrolytes may be contained in a matrix. The matrix is preferably selected from the group consisting of an aqueous polymer gel, a paste, saturated gauge, and open cell foam. Those of ordinary skill in the art know that the preceding list is non-exhaustive and other material may used as the matrix. The first electrode may be a carbon impregnated polymer and the second electrode may be a metallic foil. The insulated conductor may be preferably selected from the group consisting of metallic wire, metallic foil, carbonized film, and carbonized rubber, though this is not an exhaustive list. The first electrolyte solution may be dilute aqueous solutions of chemicals selected from the group consisting of hydrogen peroxide, magnesium hydroxide, and iodine, while the second electrolyte solution may be dilute aqueous solutions of chemicals selected from the group consisting of saline (sodium chloride), magnesium chloride, magnesium hydroxide, or other biocompatible electrolytes. The first electrolyte, the second electrolyte, and the conductor may be provided in an adhesive patch which can be attached to the body. Preferably, the body is a human body. In this preferred embodiment the first and the second electrolyte may have an ionic gel positioned between the reagents and the contact of the reagents with the body.

A "matrix" is a composition in which a solution reagent is contained, so as to enable the

solution to be handled and placed in contact with the body at a confined location. Matrices include, but are not limited to gels, pastes, organic and inorganic fibers (such as gauze), and foams.

"Insulated conductor" is a material that allows for the flow of electrons between the first and second electrodes but not between the conductor and the body.

By "adhesive patch" is meant a bandage to which the components of the device are attached(first electrode/electrolyte pair, second electrode/electrolyte pair and optionally a conductor) which is able to adhere to a body surface.

III. Bandages

In a preferred embodiment, the bandage comprises an inner and an outer surface, a first electrode/electrolyte pair and a second electrode/electrolyte pair of different electrode potentials, the first electrode/electrolyte pair attached to the inner surface of the bandage at a first location on the bandage, the second electrode/electrolyte pair attached to the inner surface of the bandage at a second location on the bandage, and the electrode of the first electrode/electrolyte pair in direct contact with the electrode of the second electrode/electrolyte pair.

In another preferred embodiment, the bandage comprises an inner and an outer surface, a first electrolyte solution and a second electrolyte solution, the first electrolyte solution located on the inner surface of said bandage at a first location on the bandage and the second electrolyte solution located on the inner surface of the bandage at a second location on the bandage, and an electrode in ionic contact with the first electrolyte at a first position on the electrode and in contact with the second electrolyte at a second position on the electrode such that the first electrolyte in contact with the electrode has a different electrode potential than the second electrolyte in contact with the electrode.

The first and the second positions on the single electrode are physically separated.

In even further preferred embodiments; an insulator is positioned where the electrodes contact each other so that the insulator prevents electrical contact with the body when the

bandage is contacted with the body; the bandage further comprises at least one adhesive surface located on the inner surface of the bandage.

By "adhesive surface" is meant a sticky surface that allows for adhesion of the bandage to the surface of the body.

In a preferred embodiment, the bandage comprising an inner surface and an outer surface, a first electrode/electrolyte pair and a second electrode/electrolyte pair of different electrode potential, the first electrode/electrolyte pair attached at a first position on the inner surface of the bandage and a second electrode/electrolyte pair attached at a second position on the inner surface of the bandage and a conductor establishing an electrical connection between the electrodes of the first and the second electrode/electrolyte pair. Preferably, the conductor is positioned on the inner surface of the bandage or between the inner and outer surfaces of the bandage.

EXAMPLES

The following Examples are provided for further illustrating various aspects and embodiments of the present invention and are in no way intended to be limiting in scope. The present invention is meant to include the use of equivalent material known to those in the art and those in the art are aware that other configurations of such materials will result in the present invention.

Example 1: Devices

The devices of the present invention can assume many configurations. Some of these are described below. These illustrations are not meant to be limiting, as those of ordinary skill in the art will readily appreciate and be able to construct other suitable configurations of the present invention based on the descriptions provided.

One configuration of the claimed device is illustrated in FIG. 1. The electrolyte (1) of the first electrode/electrolyte pair and the electrolyte (3) of the second electrode/electrolyte pair are in ionic contact with the body at separate locations on the body and contained in a gel or matrix.

The electrode (2) of the first electrode/electrolyte pair is in contact with the electrolyte (1) and the electrode (4) of the second electrode/electrolyte pair is in contact with the second electrolyte (3). The first electrolyte solution (1) is located on the exterior surface of the body at the region through which it is desirous for electric current to flow (6). Such a site could be a wound bed on the exterior surface of the body (see FIG. 4). The second electrolyte (3) is in contact with and located on the exterior surface of the body at a location (7) that is physically separate from the first location (6). The first electrode (2) and second electrode (4) are connected by an insulated conductor (5). The first electrode/electrolyte pair can be of higher or lower electrode potential than the second electrode/electrolyte pair.

FIG. 2 illustrates a configuration of the claimed invention in which the electrode (2) of the first electrode/electrolyte pair makes direct contact with the electrode (4) of the second electrode/electrolyte pair. At the area of contact of the electrodes (5), there is an insulator (8) positioned between the electrodes (2) and (4) and the exterior body surface.

The electrolyte (1) of the first electrode/electrolyte pair and the electrolyte (3) of the second electrode/electrolyte pair are in ionic contact with the body at separate locations on the body and contained in a gel or matrix. In the first electrode /electrolyte pair the electrode (2) is in contact with the electrolyte (1), but not directly with the body. In the second electrode/electrolyte pair the electrode (4) is in contact with the electrolyte (3), but not directly with the body. The first electrolyte solution (1) is located on the exterior surface of the body at the region through which it is desirous for electrical current to flow (6). Such a site could be a wound bed on the exterior surface of the body (see FIG. 4). The second electrolyte (3) is in contact with and located on the exterior surface of the body at a location (7) that is physically separate from the first location (6). The first electrode/electrolyte pair can be of higher or lower electrode potential than the second electrode/electrolyte pair depending on the desired polarity of the external current.

A further embodiment of the claimed invention is illustrated in FIG. 3., in which a single electrode (2) is shared by both electrode/electrolyte pairs. The electrode (2) is in contact with the

first electrolyte (1) at a first location on the electrode (4) and is in contact with the second electrolyte (3) at a second location on the electrode (5). The first electrolyte (1) and the second electrolyte (3) are in ionic contact with the body at separate locations on the body and contained in a gel or matrix. The first electrolyte solution (1) is located on the exterior surface of the body at the region through which it is desirous for the electrical current in the body to flow (6). Such a site could be a wound bed on the exterior surface of the body (see FIG. 4). The second electrolyte (3) is in contact with and located on the exterior surface of the body at a location (7) that is physically separate from the first location (6). In the region between the two electrolytes an insulator (8) is placed between the electrode and the body. The combination of the common electrode and the first electrolyte can be of higher or lower electrode potential than the combination of the electrode and the second electrolyte, depending on the desired polarity of the external current.

As illustrated in FIG.4, one of the electrolyte solutions (1) is positioned in a wound bed (6) and the second electrolyte solution (3) is located on the exterior surface of the body at a location (7) physically separate from the wound bed (6).

Example 2: Bandage

FIG. 5a and 5b illustrate one configuration of a bandage of the claimed invention. Fig. 5a shows a side view of the surface of the bandage. A first electrolyte solution (1) and electrode (2) is affixed at one location on the inner surface of the bandage (which is the surface that is to contact the body) so as to be able to make ionic contact with the body when the bandage is placed on the exterior surface of the body. A second electrolyte solution (3) and second electrode (4) is affixed at a position separate from the first electrolyte and electrode on the inner surface of the bandage. The first electrode (2) and the second electrode (4) are directly connected (5). An insulator (8) is located on the inner surface of the bandage to prevent contact of the first and the second electrode with the body. The outer surface of the bandage that does not make direct contact with the body is (9). The main body of the bandage (10) can consist of a materials

such as gauze or plastic film.

FIG. 6 illustrates a concentric configuration of the device. A thin circular electrolyte gel (3) occupies a central area and is encircled by a non-conductive ring of gel (8) that is encircled by a second electrolyte (1) that forms an outer ring of g el. The central electrolyte (3) is covered by a circular central electrode (4) that extends onto the non-conductive gel. A ring shaped electrode (2) contacts the central electrode (4) and extends over the outer electrolyte gel ring (1). All of the electrolyte gel and non-conductive gel materials are adhesive, thus allowing the device to adhere to the skin or subcutaneous tissues and the electrode materials. Where the two electrodes touch they also make electrical contact.

Any of the configurations of the device discussed above can be readily attached to a bandage. Attachment could be by any means known to those who practice the art, including adhesives, tape, etc.

FIG. 5b shows a bottom view of the bandage.

Example 3: The Generation of Direct Current with Materials of Different Redox Potential.

The following experiment was conducted utilizing materials suitable as electrodes and electrolytes in the present invention to measure the generation of electrode voltage and current over time.

Materials

Solutions: Acetic acid 3%
Hydrogen peroxide 3%
Sodium chloride 0.9%
Sodium bicarbonate 1%

Electrodes: Carbonized polymer sheet
Aluminum foil

Other: Four gauze pads 4"x8"
Four gauze pads 2"x4"
Polymer film (handiwrap)

The four 4"x8" gauze pads were layered to form a 4"x8"x0.25" pad. This was placed on a porcelain surface and soaked with normal (0.9%) saline. Two of the 2"x4" gauze pads were layered to form a 2"x4"x0.25" pad. This 2"x4" pad was soaked in the sodium bicarbonate solution film and placed on one end of the 4"x8" gauze pad. The remaining two 2"x2" gauze pads were layered and soaked in a solution formed by mixing acetic acid 3% with hydrogen peroxide 3% to yield a mixture of 1.5% acetic acid and 1.5% hydrogen peroxide solution. This second 2"x4" gauze pad was placed on the opposite end of the 4"x8" saline soaked pad. This gauze pad was covered with a 2"x4" carbonized polymer film. The first gauze pad soaked in bicarbonate was covered by a 2"x4" aluminum foil. The aluminum foil and carbonized polymer were connected by wire leads to a digital volt/ohm meter. The entire electrode assembly was covered with a thin polymer film to prevent evaporation. The following currents and voltages were observed over an uninterrupted 72 hour period. The assembly was utilized in the current measuring mode through out the experiment except when the voltage readings were taken over one minute stabilization periods.

In this example, the current that is measured would be external to the body if the device was present on the exterior of the body. This is similar to the current that is applied to a body by external devices. This external current is balanced or offset by the current that flows in the body, as a result of configuring the claimed invention on the body. There is a direct relationship between external current applied to the body and a current that flows within the body, such that one can ascertain whether a therapeutic level of current is present by measuring the external current.

Day	TIME	CURRENT (mA)	VOLTAGE (V)
Day 1	18:00	0.71	0.76
	23:45	0.58	0.71
Day 2	06:30	0.58	0.73
	13:00	0.60	0.75
	18:00	0.58	0.76
	23:30	0.54	0.74
Day 3	07:00	0.51	0.73
	11:30	0.49	0.73
	18:00	0.59	0.75
	23:00	0.52	0.72
Day 4	08:00	0.50	0.70
	12:00	0.49	0.73
	18:00	0.47	0.72

This experiment demonstrated very adequate voltages and currents over a 72 hour period. The currents are within the range of therapeutic currents for treatment of wounds using battery operated electronic devices. Clinical efficacy has been demonstrated with the application of as little as 0.200 mA of current delivered for several hours per day in other studies. This data indicates that nontoxic formulations can be easily constructed and that these devices can deliver more than adequate current to the site of treatment to achieve clinical efficacy.

Example 4: Construction of a Device

The selection of suitable materials (electrodes and electrolytes) for use in the device can be accomplished using several guiding principles. The materials must be biocompatible. The two electrode/electrolyte pairs when combined must have sufficiently different electrode

potentials so as to result in a net potential of adequate magnitude. The materials must be available in a form that is suitable for a topical application such as at a wound site or source of pain. Materials that meet these criteria can be easily tested. A chemistry reference such as "Handbook of Chemistry and Physics" by the CRC press provides lists of standard electrode voltage potentials for hundreds of reactions. Such a reference is useful in selecting materials for this invention because it allows one to estimate the electrode potentials of two half reactions. Lists of organic redox reactants are also available from a variety of biochemistry texts. Those of ordinary skill in the art can readily determine suitable materials for use as electrodes and electrolytes in the devices and methods of the present invention, by selecting materials that have sufficient difference in electrode potential for the generation of a desirable potential and direct current. The specific reagents (and the quantity and concentration of reagents) can be easily tested using an experimental set up as described in Example 1 to determine the level of voltage and current generated, and the duration of the current.

Examples of some common electrolytes and electrodes are given in Tables 1 and 2. Any electrode/electrolyte pair from Table 1 may be combined with any electrode/electrolyte pair from Table 2 and a suitable electrode voltage potential and current will result. The electrode/electrolyte pairs listed in Tables 1 and 2 are representative examples only. Many other biocompatible electrodes and electrolytes may be paired and used in combination to cause a suitable voltage potential for this application. An individual familiar with the art is capable of determining suitable electrode/electrolyte pairs and electrode/electrolyte pair combinations. Table 1 electrode and electrolyte combinations will undergo oxidation and result in a negative electrode potential when combined with Table 2 electrode and electrolyte combinations which in turn will undergo reduction and result in a positive electrode potential.

Table 1

Electrodes	Electrolyte Solution
Carbon	Hydrogen peroxide and acetic acid
Silver	Silver chloride
Copper	Copper chloride

Table 2

Electrodes	Electrolyte Solution
Aluminum	Hydrogen peroxide or sodium bicarbonate
Nickel	Hydrogen peroxide or sodium bicarbonate
Zinc	Hydrogen peroxide or sodium bicarbonate

The electrolytes, such as those in Tables 1 and 2 are typically used in various medical applications, and thus are biocompatible.

Various elemental metals may be considered as a negative (reducing) electrode due to their propensity to be oxidized as they dissolve into solution. Aluminum is nontoxic, stable, and has a suitably negative electrode voltage potential, is conformable as a foil and thus is a suitable material to comprise a negative electrode. Any salt solution such as sodium chloride will make a suitable electrolyte to use with an aluminum electrode. Aluminum will also react with the hydroxyl ion in a more energetic reaction thus an electrolyte solution of a dilute base, such as sodium hydroxide, will increase the negativity of the reduction potential of aluminum.

Oxidizing agents may be considered in a similar fashion for use as electrolytes with a positive electrode to be paired with the previously described negative electrodes. Again, biocompatibility, electrode potential, and ease of use are considerations. A number of oxidizing agents such as hydrogen peroxide, iodine, and carbamide peroxide are nontoxic and can be

mixed in solutions that are biocompatible. Carbon impregnated polymer can be used as an inert and nonreactive electrode with these oxidants. Silver ion from a solution of silver chloride is oxidized when it is deposited on a silver electrode. The silver, silver chloride electrode/electrolyte pair thus comprises another biocompatible positive electrode. Other metallic ions such as copper ion and gold ion may be used with their respective electrodes or an inert electrode.

Electrolyte gel solutions can be prepared, for example, by combining electrolyte solutions such as acetic acid 3% with hydrogen peroxide 3% with gelatin and paste. The mixture can be poured over wax paper to form sheets of electrolyte gel material. Electrode materials may then be placed over the gel sheets to create a sandwich like configuration that can be cut into various shapes to facilitate application to the body. The conductor which is not insulated at the terminal portions is attached at either end to the electrodes by coining or crimping or with a third metallic element or by a clasp-like mechanism. The outer surface of the electrodes facing away from the body and attachment area of the conductor are covered by an adhesive polymer that further insulates the device from unwanted conductance and to improve handling.

For example, the thickness of the electrolyte gel can vary between 1/16" to ¼". The diameter of the electrodes can vary between ½" and 6" depending on the treatment purpose. Electrolyte gel may be provided in bulk form to be added to wounds to improve conductance and to fill the wound cavity to the level of the skin surface.

The fabrication of the bandage can be performed through multiple methods and designs. One such method is to fabricate three adhesive (sticky) gel pads in the dimensions of 1"x1"x¼". First gel pad is electrolytic and weakly basic (pH 8), the second gel pad is made from de-ionized water and is non conductive and the third gel pad is electrolytic containing hydrogen peroxide and is weakly acidic (pH 6). The three gel pads are arranged in linear fashion with the non conductive gel pad in the middle. An aluminum foil 1"x1.75" is placed over the first and middle gel pad. A carbon impregnated polymer film 1"x1.75" is placed over the 3 pad and covering the aluminum electrode over the middle pad. The aluminum foil and carbon film are electrically

joined over the middle pad by coining, crimping or using a conductive glue. The foil and carbon film are covered with an adhesive non-conductive polymer film. The lower surface of the electrode system is covered with a stiff polymer film which may be removed prior to placing the device over the intended area of treatment. It would be readily apparent to those in the art, that other electrolyte solutions, as previously described, can be used in the first and third gel pads such that suitable electrode potentials are created.

Example 5: Treatment of Wounds

The treatment of a wound involves several steps. The wound is cleansed with antibacterial soap and rinsed with sterile saline in the conventional fashion. If needed, the wound cavity is filled to the surface of the nearby skin with a sterile ionic gel, such as 0.9% saline in a carboxymethylcellulose base.

A circular electrode somewhat larger than the wound opening consisting of a carbon impregnated polymer film coated with an electrolytic adhesive layer of dilute solution of hydrogen peroxide in a gel base is placed over the wound with the hydrogen peroxide gel in contact with the ionic gel placed in the wound bed and covering the wound and making a sealing contact with the surrounding skin.

An electrode of similar proportion, consisting of aluminum foil with an electrolytic adhesive layer of 1% sodium bicarbonate gel is placed against the nearby skin.

An insulated foil connective tape constructed from aluminum foil with an adhesive polymer backing is used to make an electrical connection between the carbon electrode and the aluminum foil electrode.

This configuration, with the electrode/electrolyte pair of higher potential located in the wound bed provides a positive polarity and the resultant current that flows has been demonstrated to promote wound healing. A negative polarity and negative current may be provided to the wound by reversing the placement of the two electrode/electrolyte pairs (i.e., the pair of lower potential located in the wound bed), a negative polarity would be created. The

negative current that flows as a result of this arrangement has been shown to promote the cleansing of a wound.

The current provided by the device is dependent upon the distance between the two electrodes, the quality of the nearby skin (hydration, salt content, thickness, etc.), and the quality of the wound (wetness, depth, fat content, size, etc.), but will typically range from 100 to 400 microamperes. This level of current can be maintained for more than 24 hours without changing the electrodes.

Therapeutic levels of current and protocols for the treatment for wound healing have been described (see Carley, P.J. and Wainapel, S.F., Arch Phys Med Rehabil 66:443, 1985; Mulder, G.D., Arch Phys Med Rehabil 72:375, 1991; Wolcott, L.E., Wheeler, P.C., Hradwicke, H.M. and Rowley, B.A., Southern Med. Journal, pp. 795-801, 1969).

Example 6: Treatment of Other Conditions

The treatment of conditions other than wounds is simplified by the lack of need for skin cleansing and filling of a wound cavity. Areas of pain require the placement of the two electrode/electrolyte pairs such that the pair with the higher electrode potential is positioned over the area that is the source of pain. An arrangement similar to that useful for wound treatment can be employed for the treatment of pain. Appropriate areas of adhesive layers of electrolytic and non conductive gels form the undersurface of the electrode configuration so that the device may be placed on the skin over painful areas as needed for up to 24 hours at a time.

Those of ordinary skill in the art would be familiar with treatment protocols for pain, including length of treatment and required current levels.

CONCLUSION

One skilled in the art would readily appreciate that the present invention is well adapted to carry out the objects and obtain the ends and advantages mentioned, as well as those inherent therein. The molecular complexes and the methods, procedures, treatments, molecules, specific compounds described herein are presently representative of preferred embodiments are exemplary and are not intended as limitations on the scope of the invention. Changes therein and other uses will occur to those skilled in the art which are encompassed within the spirit of the invention are defined by the scope of the claims.

It will be readily apparent to one skilled in the art that varying substitutions and modifications may be made to the invention disclosed herein without departing from the scope and spirit of the invention.

All patents and publications mentioned in the specification are indicative of the levels of those skilled in the art to which the invention pertains. All patents and publications are herein incorporated by reference to the same extent as if each individual publication was specifically and individually indicated to be incorporated by reference.

The invention illustratively described herein suitably may be practiced in the absence of any element or elements, limitation or limitations which is not specifically disclosed herein. Thus, for example, in each instance herein any of the terms "comprising", "consisting essentially of" and "consisting of" may be replaced with either of the other two terms. The terms and expressions which have been employed are used as terms of description and not of limitation, and there is no intention that in the use of such terms and expressions of excluding any equivalents of the features shown and described or portions thereof, but it is recognized that various modifications are possible within the scope of the invention claimed. Thus, it should be understood that although the present invention has been specifically disclosed by preferred embodiments and optional features, modification and variation of the concepts herein disclosed may be resorted to by those skilled in the art, and that such modifications and variations are considered to be within the scope of this invention as defined by the appended claims.

In addition, where features or aspects of the invention are described in terms of Markush groups, those skilled in the art will recognize that the invention is also thereby described in terms of any individual member or subgroup of members of the Markush group. For example, if X is described as selected from the group consisting of bromine, chlorine, and iodine, claims for X being bromine and claims for X being bromine and chlorine are fully described.

The invention has been described broadly and generically herein. Each of the narrower species and subgeneric groupings falling within the generic disclosure also form part of the invention. This includes the generic description of the invention with a proviso or negative limitation removing any subject matter from the genus, regardless of whether or not the excised material is specifically recited herein.

Other embodiments are within the following claims.

What is claimed is:

CLAIMS

1. A device for generating a voltage potential on a body and causing an electrical current to flow in said body, consisting essentially of:

(a) a first electrode;

(b) a second electrode;

(c) a first electrolyte; and

(d) a second electrolyte;

wherein

(i) said first electrode and said first electrolyte form a first electrode/electrolyte pair;

(ii) said second electrode and said second electrolyte form a second electrode/electrolyte pair;

(iii) said first electrode/electrolyte pair has a different electrode voltage potential than said second electrode/electrolyte pair;

(iv) said electrolyte of said first electrode/electrolyte pair is in ionic contact with a first region of said body;

(v) said electrolyte of said second electrode/electrolyte pair is in ionic contact with a second region of said body; and

(vi) said first electrode is in contact with said second electrode;

wherein said contact establishes an electrical connection only between the electrodes of said first and said second electrode/electrolyte pairs; or

provided that there is no external power source.

2. The device of claim 1, wherein said contact between said first electrode and said second electrode is made by a conductor.

3. The device of claim 1, wherein said contact between said first electrode and said second electrode is made by a direct physical contact between said first and second electrodes.

4. The device of claim 1, wherein

(a) said first electrolyte and said second electrolyte are of different chemical composition, wherein

(i) said first electrolyte solution is in ionic contact with a first region of said body, and

(ii) said second electrolyte is in ionic contact with a second region of said body, and

(b) said contact between said first electrode and said second electrode is made by having said first and second electrodes be one and the same, wherein a first position on said electrode is in ionic contact with said first electrolyte and a second position on said electrode is in ionic contact with said second electrolyte, said electrode not in ionic contact with said body.

5. The device of claim 1, wherein said device is a bandage having an inner surface and an outer surface.

6. A method for generating a voltage potential on a body and causing an electrical current to flow in said body, comprising

(a) providing a first electrode;

(b) providing a second electrode;

(c) providing a first electrolyte; and

(d) providing a second electrolyte;

wherein

(i) said first electrode and said first electrolyte form a first electrode/electrolyte pair;

(ii) said second electrode and said second electrolyte form a second electrode/electrolyte pair;

(iii) said first electrode/electrolyte pair has a different electrode voltage potential than said second electrode/electrolyte pair;

(iii) said first electrode/electrolyte pair has a different electrode voltage potential than said second electrode/electrolyte pair;

(iv) said electrolyte of said first electrode/electrolyte pair is in ionic contact with a first region of said body;

(v) said electrolyte of said second electrode/electrolyte pair is in ionic contact with a second region of said body; and

(vi) said first electrode is in contact with said second electrode;

wherein said contact establishes an electrical connection only between the electrodes of said first and said second electrode/electrolyte pairs; or

provided that there is no external power source.

7. The method of claim 6, wherein said contact between said first electrode and said second electrode is made by a conductor.

8. The method of claim 6, wherein said contact between said first electrode and said second electrode is made by a direct physical contact between said first and second electrodes.

9. The method of claim 6, wherein

(a) said first electrolyte and said second electrolyte are of different chemical composition, wherein

(i) said first electrolyte solution is in ionic contact with a first region of said

body, and

(ii) said second electrolyte is in ionic contact with a second region of said body, and

(b) said contact between said first electrode and said second electrode is made by having said first and second electrodes be one and the same, wherein a first position on said electrode is in ionic contact with said first electrolyte and a second position on said electrode is in ionic contact with said second electrolyte, said electrode not in ionic contact with said body.

10. A method for treating a patient with a condition amenable to treatment by the generation of a voltage potential and the flow of electrical current in the patient's body comprising the administration of the method of claim 6.

11. A method for promoting wound healing by generating a voltage potential and causing electrical current to flow through a wound bed comprising the administration of the method of claim 6.

12. A method for promoting wound cleansing by generating a voltage potential and causing electrical current to flow through a wound bed comprising the administration of the method of claim 6.

13. A kit for generating a voltage potential on a body and causing an electrical current to flow in said body, comprising:

(a) a biocompatible first electrolyte;

(b) a biocompatible second electrolyte, and

(c) a biocompatible first electrode.

14. The kit of claim 13, further comprising:

(d) a biocompatible second electrode; and

(e) a conductor;

wherein

(i) said first electrode and said first electrolyte form a first electrode/electrolyte pair;

(ii) said second electrode and said second electrolyte form a second electrode/electrolyte pair; and

(iii) said first electrode/electrolyte pair has a different electrode voltage potential than said second electrode/electrolyte pair.

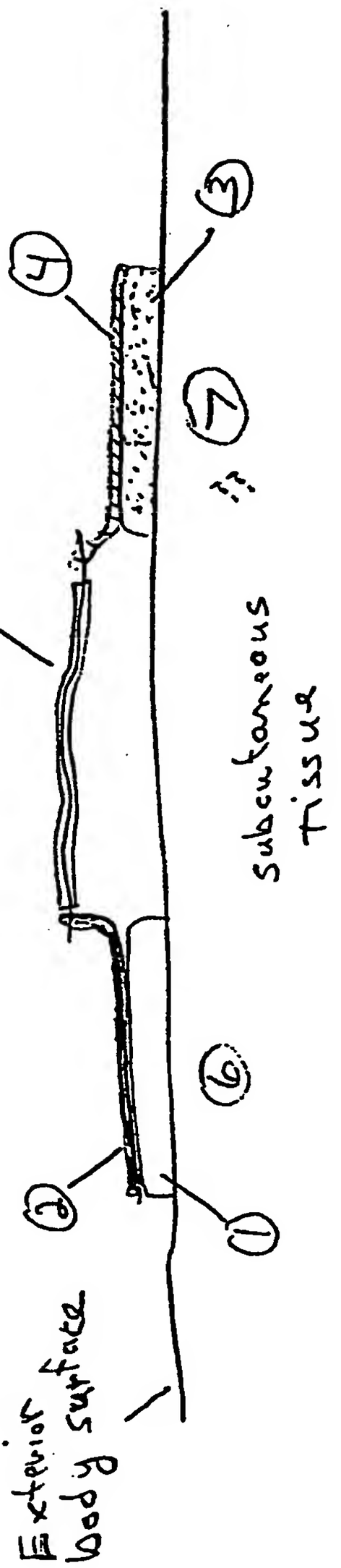


Fig. 1

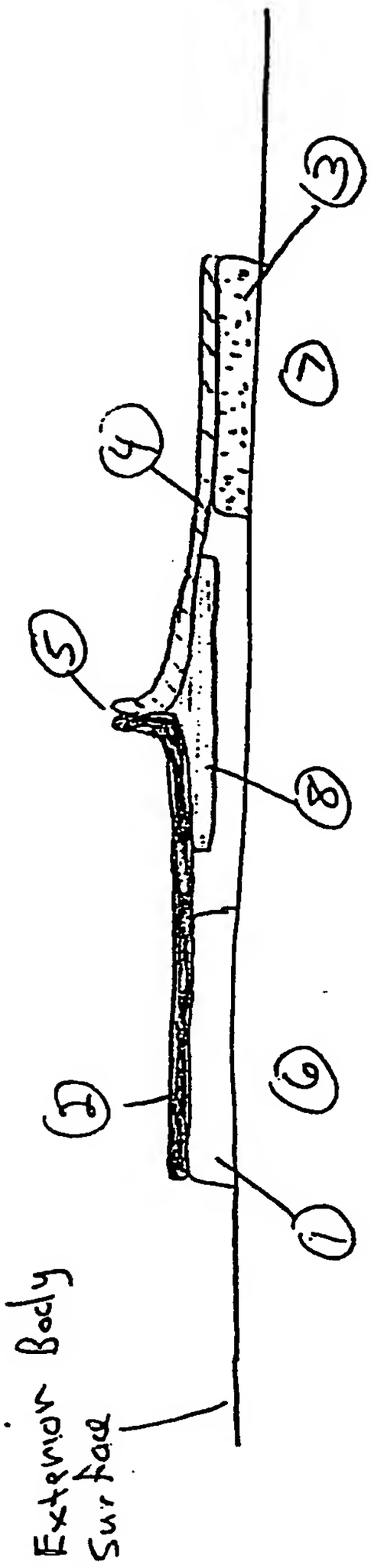


FIG 2

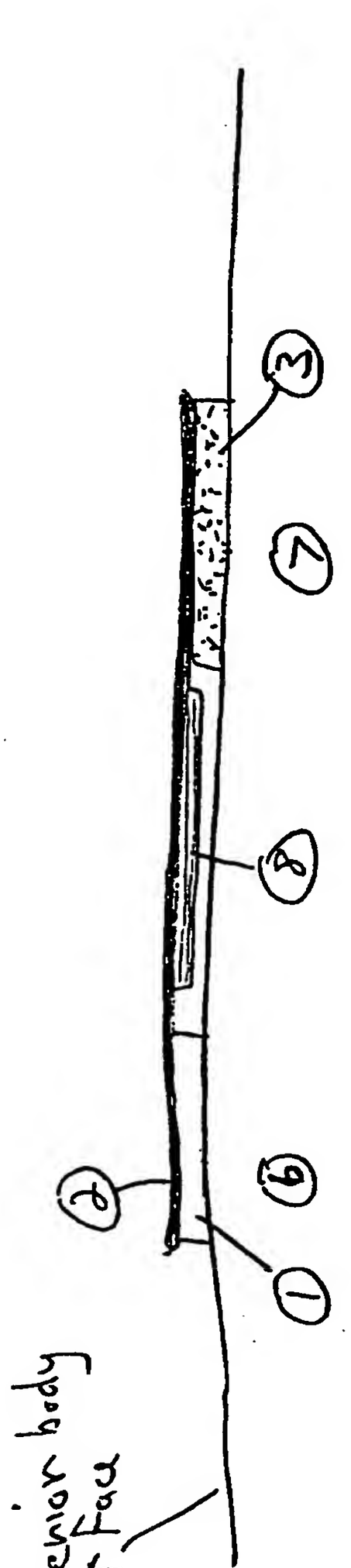


Fig 3

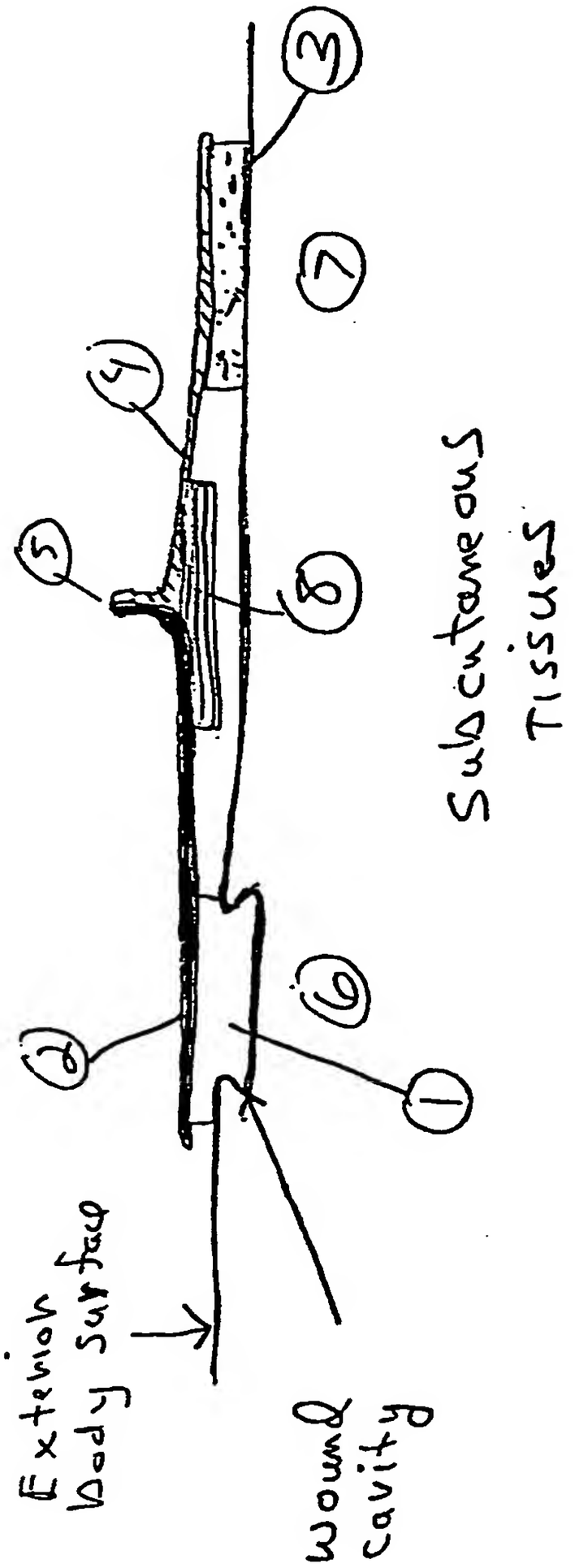

3
7
1
5
6
9
8
1
Subcutaneous Tissues
Extension Body Surface
Wound cavity

Fig 4

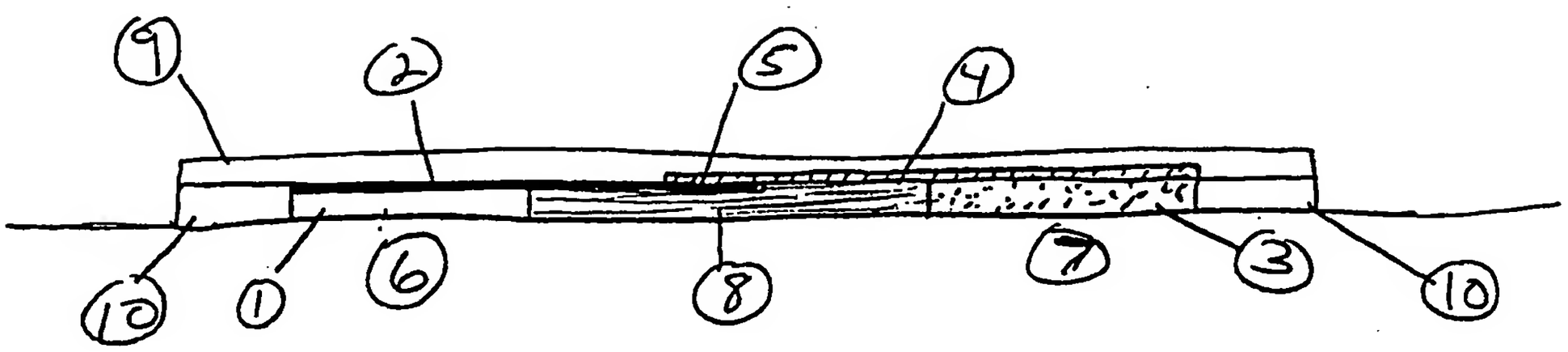


Fig 5a

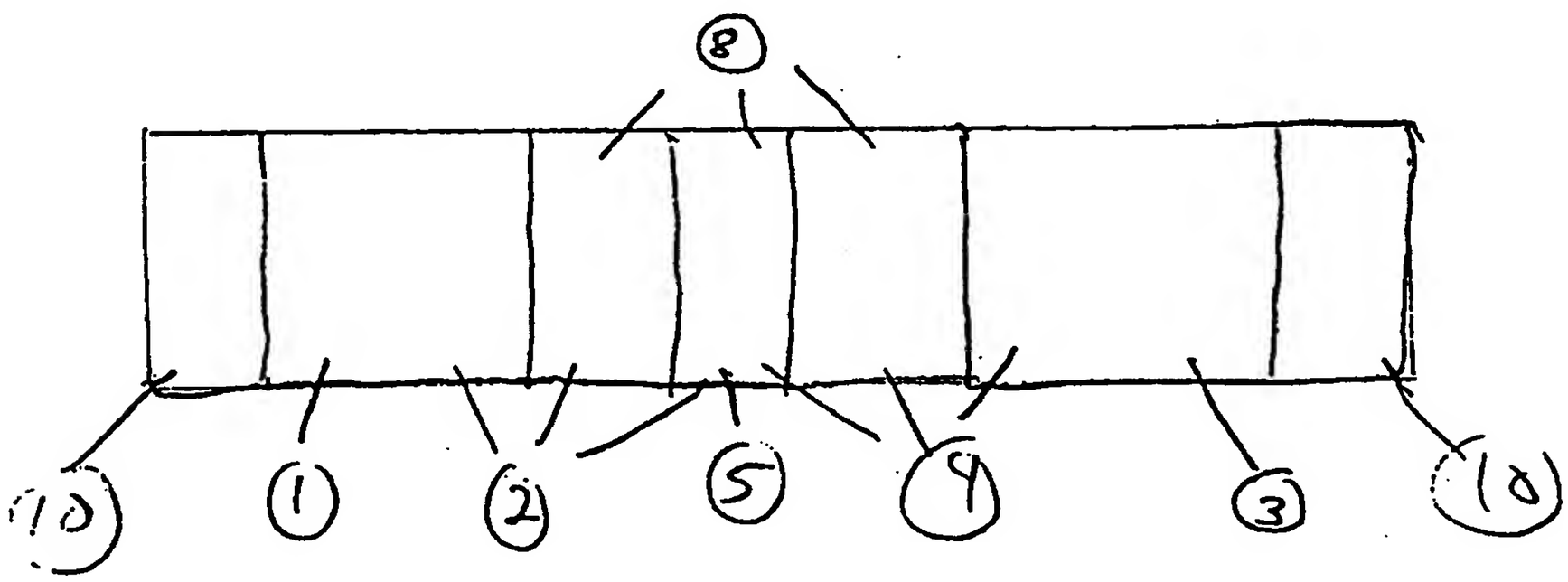


Fig 5b

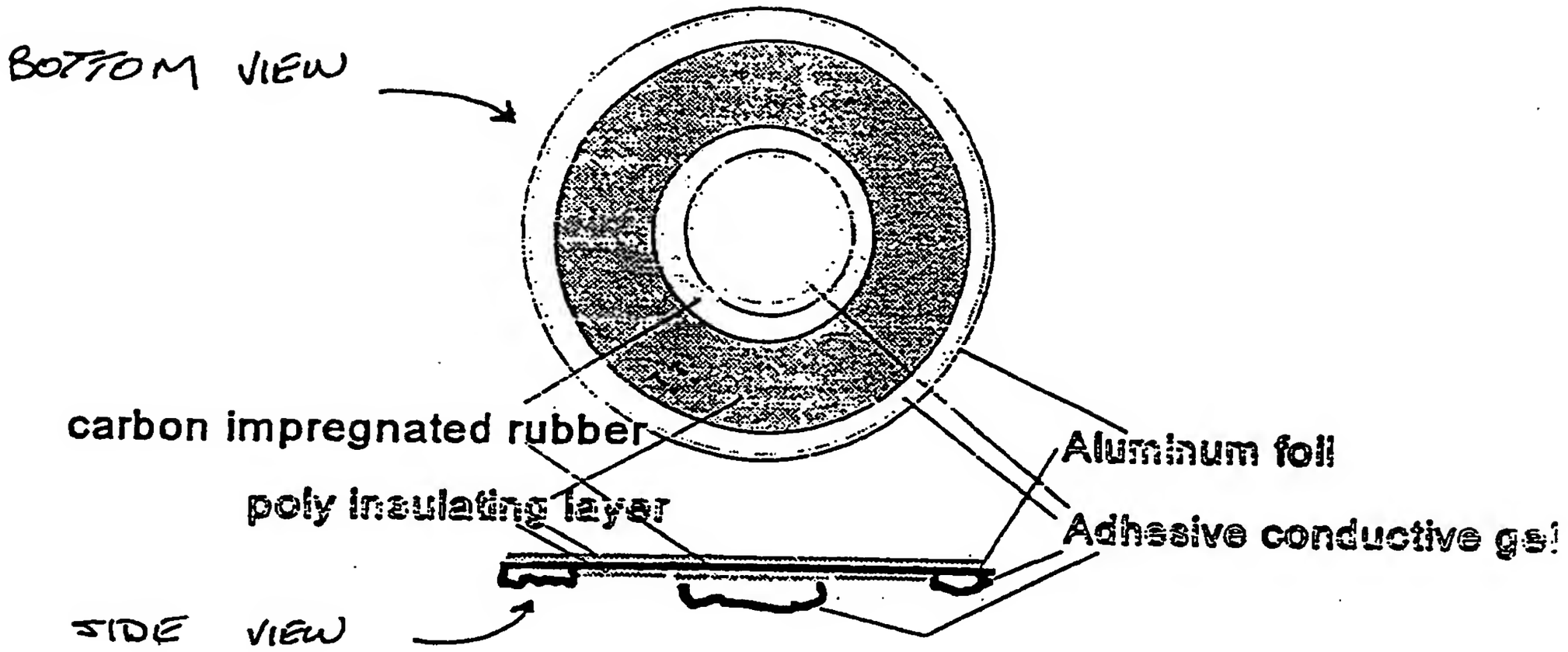

BOTTOM VIEW
carbon impregnated rubber
poly insulating layer
Aluminum foil
Adhesive conductive gel
SIDE VIEW

FIG. 6

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 00/23218

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 26942 A (MINNESOTA MINING & MFG) 31 July 1997 (1997-07-31) page 5, line 5 -page 6, line 8 page 7, line 6-24	1-4,6-9, 13,14
X	US 5 354 321 A (BERGNER MARIO) 11 October 1994 (1994-10-11) column 3, line 21-45	1,2,6,7, 13,14
X	DE 195 03 341 A (BERGNER ANNEKATHRIN) 13 July 1995 (1995-07-13)	1,2,6,7
A	the whole document	5,13,14
A	GB 1 588 933 A (SEIDERMAN M) 29 April 1981 (1981-04-29) the whole document	5

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"P" document published prior to the international filing date but later than the priority date claimed

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 January 2001	19/01/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Grossmann, C.

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

...formation on patent family members

Interr ...nal Application No
PCT/US 00/23218

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